



INSTITUTE OF FOOD TECHNOLOGISTS

THE SOCIETY FOR FOOD SCIENCE AND TECHNOLOGY

BRUCE R. STILLINGS, Ph.D. / President, 1998-1999

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August 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 99N-1174
Re: Dietary Supplements; CFSAN Strategy

Dear Sir or Madam:

The Institute of Food Technologists (IFT) appreciates the opportunity to provide the Food and Drug Administration (FDA) input into the Center for Food Safety and Applied Nutrition (CFSAN) as it develops its strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act. IFT believes it is critical that consumers are assured access to safe dietary supplements that are truthfully and not misleadingly labeled.

IFT maintains a strong interest in dietary supplements issues and appreciated the opportunity to participate in the June 8 public meeting in Washington, D.C. In this letter IFT wishes to supplement the verbal remarks that Dr. Mary Ellen Camire of the University of Maine made in its behalf during the meeting.

IFT agrees in general with the priorities of CFSAN's dietary supplement program. IFT recommends, however, that the agency place emphasis on work in progress. For example, IFT recommends that the agency complete the rulemaking that addresses dietary supplements containing ephedrine alkaloids, despite the recent legal decision in the matter. Supplements containing hormonal products, such as androstenedione, are a concern as well.

Specific comments follow:

Boundaries Between Dietary Supplements and Foods, Drugs, and Cosmetic Products and Claims

IFT suggests that the agency provide manufacturers with specific guidance or advice on how to differentiate between foods and supplements. Key issues that need addressing are: use of structure-function claims for foods, use of dietary ingredients such as botanicals in foods, and whether supplements may make claims regarding sensory attributes such as flavor and texture.

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Research Needs

Because very little is known about why and how individuals use dietary supplements, IFT recommends that the agency allocate research resources to consumer research. Consumer perception of structure-function claims also needs study.

Enforcement

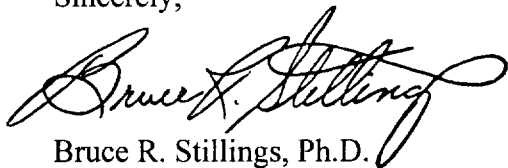
IFT suggests that CFSAN permit premarket notification within the statutory time frame for supplements containing new dietary ingredients and structure-function claims. Further, IFT believes that issuing a notice or rule describing what constitutes an authoritative statement that would adequately substantiate a nutrient content/health claim as provided for under the FDA Modernization Act is important.

Resource Needs

IFT recommends that an advisory panel on dietary supplements, similar to that for foods, be established to provide FDA with scientific expertise and consumer views in botanicals and other dietary ingredients as well as advisement on supplement issues.

Thank you for considering IFT's comments.

Sincerely,

A handwritten signature in black ink, reading "Bruce R. Stillings". The signature is fluid and cursive, with the first name "Bruce" and last name "Stillings" clearly legible.

Bruce R. Stillings, Ph.D.
President

IFT is the scientific society for food science and technology with 28,000 individual members working in the food system in the private sector, government, and academia. IFT's mission is to advance the science and technology of food through the exchange of knowledge.

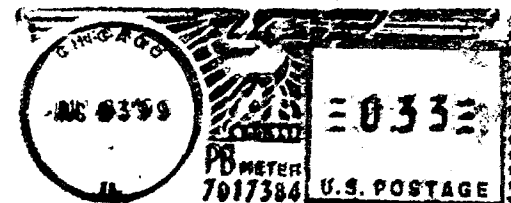


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Address Correction Requested



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